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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,815	01/07/2002	Leonard Harrison	10308B	4822

7590 02/25/2005

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,815	HARRISON ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-29, 37-40* is/are pending in the application.

4a) Of the above claim(s) *15,19-29 and 37-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I in the paper filed 1/10/05 is acknowledged. Applicant's election with traverse of the peptide of Claim 14, X_2 is SEQ ID NO:1, is acknowledged.

Applicant argues that the inventions are not independent and distinct. Applicant further argues that the inventions are interrelated and interdependent.

These arguments are not found persuasive for the following reasons. "Independent and distinct" has been defined (as set forth in the MPEP) to encompass independent *or* distinct. Clearly a product and a method of its use are distinct inventions. While the search of a product and a method of its use may overlap, they are not coextensive. Whereas a product comprises only physical and structural limitations, a method of use encompasses numerous other limitations that might include timing, concentration, etc. Accordingly, a showing of noncoextensive searches has been accepted by the Office as a showing a serious search burden on the Examiner. Additionally, the issues of examination must also be considered. The issues involved in the examination of a product and specific method of said product's use are clearly different. Again, issues that might include timing, concentration, etc., not necessarily considered in the examination of a product, become critical in the examination of a method of use.

Finally note that the Office has recently formalized a policy on the rejoinder of methods of use upon the allowance of a product. However, in the instant case, Applicant has elected the method of use, thus, rejoinder practice does not apply.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 19-29 and 37-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claim 15 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims 8-14 and 16-18 read on the elected invention and are being acted upon.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-14 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) In Claim 8, "peptid3e" would properly be "peptide",
B) In Claim 16, "DDM" would properly be "IDDM".
C) In Claims 8 and 16, the recitation of a method of "assaying activity comprising ... determining reactivity", comprises a circular method comprising no actual steps for which the metes and bounds of the claims cannot be established. Also note that "reactivity" is not defined in the specification.

5. Claims 8-14 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Note that all claims ultimately depend from independent Claims 8 and 16. Claims 8 and 16 recite a method for "assaying activity comprising ... determining reactivity". The omitted steps comprise some sort of active method steps that would result in said assaying. As none of the claims comprise any actual method steps, it is unclear precisely what is actually encompassed by the claimed method.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 8-14 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of "chemical equivalents" of the peptides employed in the claimed methods, nor peptides "derived from" the peptides employed in the claimed methods, nor "derivatives" of the peptides employed in the claimed method, nor "derivative chemical equivalents" of the peptides employed in the claimed method.

The specification discloses just two peptides (SEQ ID NOS: 1 and 2) for use in the claimed method, both of which appear to be naturally occurring. The claims however, encompass the use of an essentially unlimited genus of derivatives, defined as encompassing any and all substitutions, deletions, and/or additions (page 4 of the specification), none of which are disclosed. Further, the terms "chemical equivalents" and "derivative chemical equivalents" are not even defined, and again, no examples are disclosed. Given the limited disclosure and the unlimited number of peptides encompassed for use in the method of claims, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

8. Claims 8-14 and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification provides insufficient evidence that any of the "chemical equivalents", peptide "derivatives", or "derivative chemical equivalents" would function in the method of the instant claims.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of

predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Regarding the "chemical equivalents", peptide "derivatives", or "derivative chemical equivalents" of the instant claims, it is noted that no such compositions are disclosed, and no guidance is provided as to how to make them. It is also noted that the specification provides insufficient guidance as to how to establish whether or not any "chemical equivalents", peptide "derivatives", or "derivative chemical equivalents" that had been produced would actually function in the method of the instant claims. Thus, the skilled artisan is left with no more than a methods of trial-and-error in producing an undefined composition (i.e., how to make) for establishing an undefined activity (i.e., how to use). As methods of trial-and-error provide no particular expectation of success with any particular composition candidate, said methods are considered to be unpredictable, thus, necessitating undue experimentation. Accordingly the disclosure is insufficient to enable the use of the compositions of the claims as it would take undue trials and errors to practice the claimed invention.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 8-13 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,674,978.

The '978 patent teaches a method of assaying the reactivity of a subject to IDDM autoantigen, said method comprising

determining the reactivity of a derivative of the peptide comprising 10 to 50, or 10 to 30, or 10-15 amino acid residues, wherein X_2 is SEQ ID NO:1, further wherein said peptide is capable of reacting with T cells and modifying their function in a T cell proliferation assay, further wherein said T cells are from subjects having preclinical or clinical IDDM (see particularly Examples 4, 5, and 8 and Table 11).

The reference clearly anticipates the claimed invention.

11. Claims 8-13 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Miyazaki et al. (February 1, 1995).

Miyazaki et al. teaches a method of assaying the reactivity of a subject to IDDM autoantigen, said method comprising determining the reactivity of a derivative of the peptide comprising 10 to 50, or 10 to 30, or 10-15 amino acid residues, wherein X_2 is SEQ ID NO:1, further wherein said peptide is capable of reacting with T cells and modifying their function in a T cell proliferation assay, further wherein said T cells are from subjects having clinical IDDM (see particularly Materials and Methods, *T cell proliferation* and Table II).

The reference clearly anticipates the claimed invention.

12. No claim is allowed. The use of the peptide wherein X_2 is SEQ ID NO:1 appears to be free of the prior art.

13. In the paper filed 1/07/02 Applicant indicates that an IDS including a Form 1449 has been submitted. However, no Form 1449 has been found in the file.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications

is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/21/08

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